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IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
	:	
Applicant: Baron et al.	:	**SOLUBLE EPIDERMAL GROWTH FACTOR RECEPTOR-LIKE PROTEINS AND THEIR USES IN CANCER DETECTION METHODS**
	:	
Serial No. 09/676,380	:	
	:	
Filed: 09/29/2000	:	
	:	
Examiner: C. Borgeest	:	
	:	
Atty Docket No. 99-057	:	

Pittsburgh, Pennsylvania
May 18, 2006

AMENDMENT AND RESPONSE

On April 18, 2006, the Examiner mailed an Advisory Action for the above-captioned application. The Advisory Action indicated that claims 18-23 are allowed, but noted that a new copy of the claims was not submitted. A new copy of the claims is submitted herewith.

The Examiner declined to enter the amendment stating that it raised new matter and stated that it broadened the claims from female to patient and from ovarian carcinoma to carcinoma. A review of the amendment does not indicate that it changed the scope of the pending claim. Claim 9 always applied to "patient." However, in the spirit of cooperation, Applicants submit this substitute amendment, which omits the step (correlation with carcinoma) that the Examiner found objectionable. Thus, the amendment does not enter any new matter and Applicants respectfully request that it be entered for purposes of facilitating the appeal.

Claim 9. An assay for determining the concentration of epidermal growth factor receptor in a biological sample from a human patient, the assay comprising:

a) obtaining a biological sample from the patient;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the patient biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding domain of sErbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not competitively inhibit the binding of the first purified antibody;

d) detecting the co-presence of the first and second labels to determine the concentration of the epidermal growth factor receptor complexed with the antibodies; wherein one of the antibodies is chosen from the group consisting of: MAb R.1 and antibodies with competitively inhibit the binding of MAb R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of MAb 528 and antibodies which competitively inhibit the binding of MAb 528 to ErbB1;

e) comparing the concentration of epidermal growth factor receptor obtained in step d) with a normal value; and

f) correlating a decrease in the concentration of epidermal growth factor receptor in the patient biological sample with the presence of a carcinoma in the patient.

Claim 11. The assay of claim 9 wherein the patient biological sample is chosen from the group consisting of blood, serum and plasma.